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FOR IMMEDIATE RELEASE

Spinal Simplicity Minuteman Lumbar Spinal Stenosis Indication for Use

Spinal Simplicity's mission is to provide safe, minimally invasive solutions to treat complex spinal and orthopedic disorders.

Overland Park, KS – December 17, 2021 – Spinal Simplicity, a medical device company, today announced the much-anticipated FDA clearance of a new Indication for Use (IFU) for its Minuteman family of implants, Lumbar Spinal Stenosis. Spinal Stenosis is a narrowing of the spinal canal which can lead to back and leg pain, and tingling, numbness, pain, and weakness in the legs and feet. The addition of Lumbar Spinal Stenosis to the existing FDA cleared indications of degenerative disc disease, spondylolisthesis, trauma and tumor allows Spinal Simplicity to identify and treat a new patient population using the Minuteman device.

Spinal Simplicity's focus is on the design, development and production of orthopedic implants and instrumentation that will change the way physicians treat their patients, improve outcomes and have reproducible results. With a focus on quality, our products are designed to enhance patient care while providing physicians with a greater array of minimally invasive devices. Our innovative technology and sophisticated intellectual property portfolio are forging new territory in the spinal and orthopedic markets.

"Our team could not be more thrilled with today's news that Spinal Simplicity has been able to add Lumbar Spinal Stenosis as an FDA cleared indication for our Minuteman therapy," said Todd Moseley, CEO of Spinal Simplicity. "With this announcement, we can enable our prescribers to identify and treat patients who we believe can greatly benefit from the Minuteman implant, patients we previously were unable to help. Patient First is one of our core values and with this new FDA cleared indication, we are now able to help more patients get back to leading a normal life."

The Minuteman is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions:

- Lumbar spinal stenosis;
- degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation); and/or
- tumor.

The Minuteman is intended for use with bone graft material and is not intended for standalone use. The device may be implanted via a minimally invasive lateral approach (T1-S1).

About Spinal Simplicity

Spinal Simplicity, LLC, headquartered in Overland Park, Kansas, was founded in 2008 with a vision to be the global leader in innovative, simplified surgical solutions, delivering uncompromising quality. The company has successfully been awarded 20+ patents in the U.S. and 65+ patents outside of the U.S., with additional patent applications pending. Spinal Simplicity has regulatory clearance for the Minuteman® system in the US, Europe, and Canada. Our vision is to be the global leader in innovative, simplified surgical solutions while delivering uncompromising quality. For more information, visit www.spinalsimplicity.com.

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